

REMARKS

A. **GENERALLY**

Claims 9-39 are currently pending in the application. Claims 1-8 were previously canceled. Claims 9 and 25 have been amended. No new matter has been added.

B. **RELATED PROCEEDINGS**

This Office Action is directed to Application No. 10/654,668, which application claims priority from U.S. Patent 6,804,656 issued on October 12, 2004 (the “‘656 Patent”). The prosecution of the ‘656 Patent involved multiple reviews and a substantial list of references. The ‘656 Patent issued with claims 1-26.

In a Notice of Allowance mailed June 2, 2004, the examiner cited the following reasons for allowance of claims 30-55 (renumbered in the ‘656 Patent as claims 1-26):

The present invention comprises independent claims 30 and 46. These claims include the following features that distinguish Applicants’ invention over the prior art: utilizing a remote command center in conjunction with a workstation, to monitor and if necessary intervene in the expert critical care of critically ill patients in a plurality of geographically dispersed intensive care units twenty-four hours a day seven days a week by multiple parameters in monitoring and intervention, i.e., [through] a rules engine that use[s] more than one piece of data important to patient care stored in a database. The structure pertaining to the rules engine is set forth for example in Fig. 19 and the Specification where the rules engine (642) searches for patterns [of] data indicative of clinical deterioration on page 39-40. The examiner notes for the record that it has been argued that an intensive care unit can comprise one room on a floor. (Notice of Allowability, page 2.)

A request for reexamination of the ‘656 Patent was granted on April 7, 2005. Applicant filed amended claims resulting in the issuance of a Reexamination Certificate on September 26, 2006 granting amended claims 1-26.

A second request for ex parte reexamination of the ‘656 Patent was filed on November 20, 2006, subsequent to the conclusion of the first, earlier ex parte reexamination proceeding (Control No. 90/007,377) of the same patent. A second reexamination order was issued on January 12, 2007. The order cited *Schoenberg, David, and Kohane, et al.* (“Hypothesis-Driven Data Abstraction and Trend Templates,” Proceedings of Seventeenth Annual AMIA Annual Symposium on Computer

Appl. No. 10/654,668
Reply Dated February 22, 2007
Reply to Office Action Mailed December 7, 2006

Express Mailing Label No.:
EV 929476833 US

Applications in Medical Care, October 30-November 3, 1993) (herein, "Kohane") as supporting a determination that substantial new questions of patentability had been raised. The order further asserted that *Schoenberg '502* was not prior art as to the '656 Patent.

On January 19, 2007, Patentee filed a waiver of its right under 37 C.F.R. §1.530(b) to file a statement on the new questions of patentability cited in the order. An office action was mailed on February 6, 2007. Applicant met with representatives of the Central Reexamination Unit on February 15, 2007. On that day, Applicant also filed a response to the office action issued in the 2nd Reexamination of the '656 Patent. Subsequently, on February 16, 2007, Applicant filed a supplemental response in the 2nd Reexamination proceeding. A copy of the interview summary as provided by the examiner in the 2nd Reexamination is attached hereto.

The following additional applications claiming priority to the '656 Patent and are currently pending:

10/946,548 filed on 09-21-2004
11/061,715 filed on 02-18-2005
11/072,359 filed on 03-04-2005
11/096,189 filed on 03-31-2005
11/118,950 filed on 04-29-2005
11/200,554 filed on 08-10-2005
11/235,512 filed on 09-26-2005
11/236,103 filed on 09-26-2005
11/268,706 filed on 11-07-2005
11/268,748 filed on 11-07-2005
11/444,080 filed on 05-31-2006
11/444,081 filed on 05-31-2006
11/444,082 filed on 05-31-2006
11/444,396 filed on 05-31-2006

An office action directed to the claims of the 10/946,548 application included provisional double patenting rejections citing the 11/072,359, the 11/235,512 application, and the 11/236,103 application. In order to facilitate allowance of the present application, Applicant has filed herewith terminal disclaimers with respect to the

10/946,548 application, the 11/072,359, the 11/235,512 application, and the 11/236,103 application and a terminal disclaimer with respect to U.S. Patent 6,804,656.

C. CLAIM REJECTIONS – 35 USC §103

1. Claims 9-39 have been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,772,585 issued to Lavin et al. (hereinafter, “Lavin”) in view of U.S. Patent 4,852,570 to Levine (hereinafter, “Levine”).

Claim 9, as examined, recited the following limitations (the limitations have been labeled for ease of discussion):

9. A method for utilizing physician notes in a healthcare system comprising:
 - [A] inputting patient health data reflecting a current state of a patient and treatment objectives for the patient to an input device, wherein the patient health data is inputted via formatted input options presented by the input device and wherein the input device is connected to a network;
 - [B] receiving the patient health data in the healthcare system via the network;
 - [C] accessing the patient health care data from a remote command center associated with the healthcare system via the network;
 - [D] accessing patient data elements of the patient stored in a database from the remote command center via the network;
 - [E] creating a rule for the patient using the patient health data and the patient data elements;
 - [F] applying a rules engine to selected patient data elements stored in the database to search for patterns of data and to produce an output indicative of a change in the medical condition of the patient; and
 - [G] utilizing the output from the rules engine to determine if intervention is warranted,
 - [H] wherein the monitoring and determining if intervention is warranted for the patient is directed from the remote command center.

The office actions asserts that that Lavin teaches limitations [A] through [D] but fails to teach limitations [E] through [H]. According to the office action, limitations [E] through [H] are taught by Levine.

The office action asserts that the limitation [C] is met by the multiple clinic personnel and physicians accessing various aspects of a common database information

regarding a specific patient or a group of patient (citing Lavin, Col. 4, lines 8-10).

Applicant respectfully disagrees.

The present application claims priority from and incorporates by reference U.S. patent application Ser. No. 09/443,072, now U.S. Patent 6,804,656 (hereinafter, the “‘656 Patent”). The ‘656 patent describes the functions of a command center as follows:

Clinical data is constantly monitored and presented to the command center/remote location in real time so that the intensivist can not only monitor the video of the patient but also see the vital signs as transmitted from the bedside. The signals from the clinical data and video data are submitted to a relational database, which comprises 1) standardized guidelines for the care of the critically ill, 2) various algorithms to support the intensive care regimen, 3) order writing software so that knowledge-based recommendations and prescriptions for medication can be made based upon the clinical data, and 4) knowledge-based vital-sign/hemodynamic algorithms that key the intensivist to engage in early intervention to minimize adverse events.

The advantage of the present invention is that intensivists see all patients at a plurality of ICU's at all times. Further, there is a continuous proactive intensivist care of all patients within the ICU, thereby minimizing adverse events. Intervention is triggered by evidence-based data-driven feedback to the intensivist so that standardized care can be provided across a plurality of ICUs. (Specification of the ‘656 Patent, Col. 5, lines 11-30.)

Applicant respectfully submits that when viewed in the light of the disclosure of the present application, the access of a common database by multiple clinic personnel and physicians does not teach a “remote command center.”

The office action asserts that Levine teaches a microcard reader and keyboard selection terminal that can be used to compare and detect a “trend” analysis from tests performed on a patient. Additionally, the office action asserts that Levine teaches that individual readings and test results can be processed mathematically to produce an output that can be used by a physician to determine if intervention with a patient is warranted. From these characterizations of Levine, the office action determines that it would be obvious for one skilled in the art to include creating and applying rules to patient data to produce an output report to a physician as taught by Levine with the system and method for managing medical records taught by Lavin.

Lavin describes a system for recording medical data from a patient over a relatively long period of time and then analyzing the collected data to detect trends. The analysis performed at "regular long term intervals:"

At regular long term intervals, that may be annually, the individual consults with a physician for an examination. At this time the physician has available for read-out and comparison, the cumulative results of the periodically made groups of tests. By comparing like measurements taken of that individual over many spaced periods of time, the doctor can more readily detect changes and "trends" that have progressively taken place over the long term. (Levine, Col. 2, lines 33-45.)

Applicant respectfully submits that the "trends" described by Levine do not equate to creating a rule for a patient and searching for patterns of data and to produce an output indicative of a change in the medical condition of the patient as recited in claim 9.

To further clarify claim 9, Applicant has amended claim 9 to recite, "creating a rule for the patient using the patient health data and the patient data elements," "applying the rule continuously to selected patient data elements stored in the database to search for patterns of data and to produce an output indicative of a change in the medical condition of the patient," and "wherein the monitoring and determining if intervention is warranted for the patient occurs in an automated fashion at the remote command center 24 hours per day 7 days per week." This limitation is fully supported by the '656 Patent, which patent was incorporated by reference in the present application.

Applicant respectfully submits that Lavin does not teach or reasonably suggest creating a rule from the patient health data collected from the physician notes and continuously applying that rule against patient data elements.

Independent claim 25 has been amended to recite similar limitations.

Based on the foregoing, Applicant submits that independent claims 9 and 25 (as amended) are not anticipated by Lavin and are therefore allowable over the cited prior art. Further, claims 10-24, which depend directly or indirectly from claim 9, and claims 26-39, which depend directly or indirectly from claim 25, are also patentable over the cited prior art.

Appl. No. 10/654,668
Reply Dated February 22, 2007
Reply to Office Action Mailed December 7, 2006

Express Mailing Label No.:
EV 929476833 US

D. CONCLUSION

Applicant respectfully submits that this amendment places the claims in condition for allowance and requests reconsideration of the current rejection of the claims now pending in this application. Should any further questions arise concerning this application or in the event the above amendments do not place the application in condition for allowance, applicant respectfully requests a telephone interview. Attorney for the applicant may be reached at the number listed below.

Respectfully submitted,



Jon L. Roberts, Ph.D., J.D.
Registration No. 31,293
Elliott D. Light, J.D.
Registration No. 51,948
Roberts Mardula & Wertheim, LLC
11800 Sunrise Valley Drive, Suite 1000
Reston, VA 20191-5302
(703) 391-2900